

## REMARKS

In the aforesaid Office Action, claims 33-36, 38 and 41 were rejected under 35 USC 103(a) as being unpatentable over Trotta (5,620,649) alone, and claims 33-37, 41 and 42 were rejected under 35 USC 103(a) as being unpatentable over Zhong (6,048,620) alone, and claim 39 was rejected under 35 USC 103(a) as being unpatentable over Trotta in view of Zhong, and claim 40 was rejected under 35 USC 103(a) as being unpatentable over Trotta in view of Okuda et al. Claims 33-36 and 38-48 are pending (claims 43-48 being added by this amendment).

The Examiner rejected claims 33-37, 41 and 42 under 35 USC 103(a) as being unpatentable over Zhong, stating that the balloon part of Zhong corresponds to the second layer of the claimed invention, the first coating of Zhong corresponds to the covalently bonded functionality of the claimed invention, the second coating of Zhong corresponds to the first layer of the claimed invention, and that although Zhong does not teach that their first coating has a thickness of about 10 to 150 nanometers, it would have been obvious to optimize the thickness of the first coating (the covalently bonded functionality of the claimed invention) as taught by Zhong given that the coating thickness of a coating can be controlled to obtain specific properties and it is desirable to obtain a thin coating thickness for a bonding layer.

However, Zhong does not disclose or suggest a plasma polymerized acrylic acid film covalently bonded to the first layer (as in claim 42), or a plasma polymerized deposited acrylate or fragmented acrylate polymer covalently bonded to the first layer (as in claim 33). In Zhong, the first coating (which the Examiner states corresponds to the covalently bonded functionality of the claimed invention) has an excess of polyfunctional cross linking agent which bonds to the second coating (the second coating corresponding to the first layer of the claimed invention). Specifically, Zhong discloses applying to a substrate a first coating which includes a dispersion or emulsion of a polymer containing an organic acid functional group and an excess of a polyfunctional cross-linking agent which is reactive with the organic acid groups of the dispersed/emulsified polymer to

crosslink the polymer and covalently bond to the subsequently applied second coating (see col. 6, lines 12-21).

The Examiner states that, in Zhong, examples of organic acid groups include carboxylic acid groups and examples of the first coating composition include acrylic copolymer dispersions. However, these organic acid groups and first coating compositions referred to by the Examiner relate to the dispersed or emulsified polymer of the first coating, and not to the polyfunctional crosslinking agent of the first coating. In Zhong, the first coating polymer containing an organic acid functional group does not covalently bond to the second coating. Instead, Zhong discloses that the polyfunctional cross linking agent of the first coating covalently bonds the second coating to the first coating. Thus, Zhong does not disclose or suggest a plasma polymerized acrylic acid film covalently bonded to a balloon layer as in claim 42, or a deposited plasma polymerized acrylate or fragmented acrylate polymer covalently bonded to the first layer as in claim 33. The plasma polymerization process provides the energy required to produce the polymerized acrylic acid/acrylate film, which at least in one embodiment is a crosslinked thin film in the range of 10 to 150 nm, which covalently bonds to the substrate/first layer without requiring a polyfunctional crosslinking agent added thereto, unlike Zhong.

Moreover, new claim 44 requires that the plasma polymerized film is covalently bonded to an outer surface of the substrate. In contrast, Zhong only discloses that the first coating (which the Examiner states corresponds to the plasma polymerized functionality) has the second coating applied to an outer surface of the first coating, so that the first coating is therefore only covalently bonded to an inner surface of the second coating. Although the first coating of Zhong is on an outer surface of the substrate/balloon, it is not covalently bonded to the substrate/balloon.

Moreover, claim 36 as amended requires a layer of adhesive between the plasma polymerized film and the second layer of the balloon to adhesively bond the first and second layers together (see also new claim 46 requiring a layer of adhesive between the plasma polymerized acrylic acid film and the agent or polymeric layer. In contrast, in

Zhong, an excess of polyfunctional crosslinking agent within the first coating bonds the first and second coatings together.

The Examiner rejected claims 33-36, 38 and 41 under 35 USC 103(a) as being unpatentable over Trotta, and claim 39 under 35 USC 103(a) as being unpatentable over Trotta in view of Zhong, and claim 40 under 35 USC 103(a) as being unpatentable over Trotta in view of Okuda et al., stating that the first layers (10, 24) of Trotta correspond to the first and second layers of the claimed invention and the second layer (20) of Trotta corresponds to the covalently bonded functionality of the claimed invention, and that although Trotta does not teach that the second layer has a thickness of about 10 to 150 nm, it would have been obvious to optimize the thickness of the second layer or the covalently bonded functionality taught by Trotta for the same reasons stated above in the rejection based on Zhong.

However, Applicants have amended claim 33 to call for a deposited plasma polymerized acrylate or fragmented acrylate polymer layer covalently bonded to at least a section of a first surface of the first layer, which is not disclosed or suggested by Trotta.

Moreover, claim 36 as amended requires a layer of adhesive between the plasma polymerized film and the second layer of the balloon to adhesively bond the first and second layers together. In Trotta, the functionalized vinylic polymer (which the Examiner states corresponds to the plasma polymerized covalently bonded functionality) bonds the layers of the balloon together, and Trotta does not disclose or suggest providing an adhesive between the functionalized vinylic polymer and a layer of the balloon.

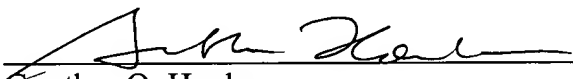
Regarding claim 38, the Examiner states that the balloon catheter of Trotta comprises an inflation lumen which is an elongated shaft as seen in Fig. 1 and thus meeting the limitations of claim 38. However, claim 38 requires that the plasma polymerized film which covalently bonds the balloon layers together has a section located between the first layer and the shaft and bonded to the shaft. Although Trotta does disclose that the Plexar resin may be used inside and outside of the catheter balloon and facilitating sealing the balloon to the catheter tube (see col. 5, lines 5-10), Trotta does

not disclose or suggest that second layer 20 (which the Examiner takes as the covalently bonded film of Applicant's claims), on an inner surface of the balloon outer layer, has a section located between the first layer and the shaft and bonded to the shaft. See paragraph [0021] of Applicant's specification for a discussion of an embodiment in which the elastomeric layer 34 does not extend the entire length of the ePTFE layer 33, and the thus exposed one or both end sections of the chemically modified ePTFE layer 33 are fusion or adhesively bonded to the shaft (not shown).

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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